

Background: Irinotecan (I) combined with Carboplatin (C) has proven to be an active combination in-patient with extensive stage SCLC. We conducted a prospective phase II study to determine the activity and safety of this combination with CT/RT in previously untreated LS-SCLC pts.

Patients and methods: The main objective was response rate (RR) and the secondary safety and overall survival. Eligibility included: measurable disease, ECOG PS 0-2, informed consent and adequate hepatic, renal and bone marrow function. Treatment consisted of: I 60mg/m² IV followed for C AUC = 3 IV D1, 8 Q 21D for 6 cycles, and concurrent RT 2.0 Gy daily to a total of 60.0 Gy, beginning in the 2nd cycle. The dose of I and C was reduced to 50 mg/m² and AUC: 2 respectively during CT/RT (cycles: 2nd - 4th). Patients with complete response (CR) received PCI (2.0 Gy X 10) after completion chemotherapy.

Results: 30 pts were enrolled, 22 male and 8 female. Median age was 71 years (range 43- 81); 76% had PS 0 or 1.

Twenty-eight pts were evaluable for response. The total number of cycles administered was 161 with a median of 6 (range 2-6). The relative dose-intensities of I and C were 84% and 87% respectively. The median of follow-up was 14 months. In intent to treat analysis the RR was 92.7%, twenty pts achieved a CR and 8 pts a PR. Median survival was 22 months. Grade 3-4 (NCI-CTC 3.0) toxicity (per cycle) included: neutropenia (14%), thrombocytopenia (14%), anemia (5%), diarrhea (12%), vomiting (5%). There were two episodes of typhitis and three episodes of febrile neutropenia, however there were no treatment-related deaths.

Conclusions: IC combined with early CR/RT is highly active with a favorable median survival. The profile of safety is adequate in pts with LS-SCLC. Further development of this combination is warranted.

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SCLC: Combined Modality Therapy Posters, Mon, Sept 3

Retrospective analysis of sequential and concurrent chemoradiotherapy of limited small cell lung cancer (SCLC)

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Background: Patients with limited disease SCLC were treated up till 2001 with sequential chemoradiotherapy (SCT) and from 2001 with concurrent chemoradiotherapy (CCT). The optimal treatment has yet to be defined. This retrospective study analysed the efficacy of both treatments.

Methods: Between 1991 until December 2000, 69 SCT pts were included, and from 2001 until February 2005 40 pts who underwent CCT. In SCT, the chemotherapy consisted of 5 cycles of cyclophosphamide, doxorubicin and etoposide. In case of complete remission, radiotherapy was given in once-daily fractions of 2.5 Gy, 5 fractions/week, to a total dose of 40 Gy. Prophylactic cranial irradiation (PCI) was given in 15 fractions of 2 Gy, 5 fractions/week.

In CCT, radiotherapy was started on day 22 after start chemotherapy. The fraction dose was 1.8 Gy, 5 fractions/week, the total dose was 45 Gy. Chemotherapy consisted of 4 or 5 cycles of cisplatin and etoposide. PCI was applied to patients who had achieved a complete response. Primary endpoints are radiological response, median survival time and

3- and 4-year overall survival; secondary endpoints include causes of death, frequency of metastases and toxicity.

The Kaplan-Meier method was applied to determine the median survival time and the survival rates.

Results: The mean and median tumour volume of SCT pts was 142 and 81cm³, those of CCT pts 117.6 and 40 cm³, resp. The mean overall treatment time of SCT was 182 d, and that of CCT 89 d.

The radiological complete response of SCT pts was 95.6%, of pts with CCT 60%. PCI was applied to 95.6% of the SCT pts and to 57.5% of the CCT pts.

The SCT median survival time was 24.9±3.0 month; the 3- and 4-year overall survival were 38.8±6.1 and 31.5±6.0%, respectively. The CCT median survival time was 23.8±4.2 month and the 3- and 4-year overall survival 36.7±8.3 and 31.5±8.6 %, respectively.

Of the 69 SCT pts, 51 had died of which 38 pts (74.5%) with tumour and 21 of 24 CCT pts (87.5%).

Grade3/4 haematological side effects were reported in 47 (68%) SCT pts and in 18 (45%) CCT pts.

Symptomatic radiation oesophagitis was observed in 41 (59%) of SCT pts and in 19 (47.5%) of the CCT pts.

Brain metastases were diagnosed in 12 (17%) SCT pts and in 13 (32.5%) CCT pts.

The mean interval time for SCT pts between restaging after chemotherapy and start of radiotherapy was 52.3 d, the median 47 d, and the range 21-173 d.

Conclusions: Although a higher mean and median tumour volume, a better radiological response was obtained for the SCT pts. The median survival time and the 3- and 4-y survival rates were not significantly different. The frequency of brain metastases in CCT pts was twice of that of SCT pts.

We advise to perform a prospective randomised trial comparing SCT and CCT. Better results might be expected with SCT schemes for smaller tumour volumes and a smaller interval time between end of chemo- and start of radiotherapy.

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Prognostic factors and management of patients with small cell lung cancer (SCLC) at the Instituto Nacional del Torax (INT) (1994 to 2001) G

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SCLC represents about 20% of LC patients in most developed countries, it has poor prognosis with 10% survival at 2 years. In this retrospective study there were 80(6%) patients with SCLC among 1274 LC patients admitted to the INT between 1994-2001. Four cases had incomplete data. We analyzed the prognostic factors, treatment, outcome and survival of the 76 cases; 63 with Limited Disease (L.D) and 13 with Extended Disease (E.D). Twelve (16%) patients did not experience weight loss and 25(33%) patients (27% in LD and 62% in ED) lost more than 10% in six months. Karnofski PS (KPS) less than 70% had 25 (33%) patients (30% with L.D and 46% with E.D)

From the 32 (42%) patients who received chemoradiotherapy (CTRT) (Cisplatin Etoposide and RT) in other oncology institutions, median